7. (Twice Amended) A method for selectively stimulating growth of lactobacilli and lactic acid bacteria in the human colon comprising administering D-tagatose to a human in an amount effective to selectively stimulate growth of lactobacilli and lactic bacteria in the human colon.

REMARKS

Claims 1-12 remain pending in this application. Claims 1 and 7 have been amended to more clearly define the subject matter which applicants regard as their invention. Specifically, the claims have been amended to point out that D-tagatose is administered in an amount effective to selectively induce the production of butyrate (claim 1) and selectively stimulate the growth of lactobacilli and lactic bacteria in the human colon (claim 7). Support for these amendments can be found in the specification, for example, in the sentence bridging pages 6 and 7, page 13 at lines 24-34, page 15, lines 15-17, and page 18 at lines 2-13. Accordingly, no new matter has been introduced by this amendment.

Applicants acknowledge, with appreciation, the personal interview conducted with Examiner Howard Owens and his supervisor Gary Geist on July 13, 2000. The arguments discussed at that interview were essentially those presented in the response to the previous Office Action, with particular emphasis on the claim limitations that D-tagatose is administered in amounts effective to selectively induce production of butyrate and to selectively stimulate growth of lactobacilli and lactic bacteria in the human colon. Because the prior art did not fairly teach or suggest that the administration of D-tagatose would selectively induce production of butyrate, it was agreed that claims 1-6 would receive favorable consideration if amended as proposed in this reply.

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During the course of the interview, it was suggested that claim 7 should be amended to address the selective production of butyrate, not the growth of bacteria. While the selective production of butyrate may be linked to the selective stimulation of the growth of lactobacilli and lactic acid bacteria, there is no scientific reason to limit or even link the process of claim 7 to selective butyrate production. As noted at various portions of the specification, for example, at page 1, lines 15-18, page 7, lines 5-7 and 21-24, page 16, lines 6-21 and Figure 5, the administration of D-tagatose has been shown to stimulate the growth of lactobacilli and lactic acid bacteria in the human colon. Figure 5 clearly demonstrates the comparative results of counting bacteria in human faeces where the individual has ingested D-tagatose and where the individual has not ingested D-tagatose. These tests clearly demonstrate that the ingestion of D-tagatose will selectively stimulate the growth of a number of lactobacilli and lactic acid bacteria in the human colon. It is respectfully submitted that these results provide a firm foundation for the subject matter of claims 7-12.

It is an established principle of patent law that inventors need not comprehend the scientific principles on which the practical effectiveness of their invention rests. *Fromson v. Advanced Offset Plate, Inc.*, 720 F.2d 1565, 1570, 219 USPQ 1137, 1140 (Fed. Cir. 1983). Through comparative tests reported in the specification and in Figure 5, applicants have demonstrated the practical effectiveness of the invention claimed in claims 7-12 . While not wishing to be limited to any theory of operation, it is now believed that the selective production of butyrate may be related to the selective stimulation of growth of lactobacilli and lactic acid bacteria in the human colon. It is entirely likely that the direct effect of administering D-tagatose is a stimulation of the

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growth of lactic acid bacteria and lactobacilli, and thus also the stimulation of their fermentation end product, lactate. Accumulation of lactate favors production of butyrate by lactate-utilizing bacteria in the environment of the human colon at a pH below 6.5. Accordingly, it is entirely possible that the direct effect of administering D-tagatose is a stimulation of the growth in lactobacilli and lactic acid bacteria, while selective production of butyrate is a secondary effect of administering D-tagatose caused by lactate.

The prior art relied upon by the Examiner fails to teach or otherwise motivate a person skilled in this art to administer D-tagatose to achieve a selective stimulation in the growth of lactobacilli and lactic acid bacteria in the human colon. As recognized by the Examiner, for example, Morelli et al. '857 shows that lactobacillus species isolated from the human colon are able to degrade a large variety of carbohydrates including well known and commercial malabsorbed carbohydrates like mannitol and maltose. This observation, however, does not mean nor is it predictable that these two carbohydrates would selectively promote growth of lactobacilli in the competitive environment of the human colon. Not only does the prior art fail to provide any motivation or suggestion to use D-tagatose to selectively stimulate the growth of lactobacilli and lactic bacteria in the human colon, it fails to provide any information that would permit a person of ordinary skill in the art to predict that success would be achieved in selectively stimulating the growth of these bacteria upon administration of D-tagatose. As the prior art relied upon by the Examiner fails to establish a *prima facie* case of obviousness, it is respectfully requested that this ground of rejection be withdrawn.

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Reexamination and reconsideration of this application in view of the amendments and remarks provided above is respectfully requested.

Please grant any extensions of time required to enter this reply and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: August 22, 2000

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